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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,233	12/31/2003	Robert L. Martuza	066683-0196	7116
22428	7590	08/06/2007	EXAMINER	
FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			SHEN, WU CHENG WINSTON	
		ART UNIT		PAPER NUMBER
		1632		
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		08/06/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/748,233	MARTUZA ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Wu-Cheng Winston Shen	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 06 July 2007.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 7-18 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 7-18 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 31 December 2003 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's After-Final amendment filed on 07/06/2007 has been received and entered.

The Examiner withdraws the finality of previous office action mailed on 04/03/2007.

***Status of claims:*** Claims 7-18 are currently under examination.

#### ***Specification***

1. Based on the Supplemental Application Data Sheet" filed on 07/06/2007, the Related U.S. Application Data are as follows:

This application is a divisional of Ser. No. 09/625,509, filed July 25, 2000, now U.S. Pat. No. 6,699,468, which is a divisional of Ser. No. 09/004,511, filed Jan. 8, 1998, which is a **continuation** of U.S. patent application Ser. No. 08/478,800, filed Jun. 7, 1995, now abandoned, which is a **continuation** of U.S. Ser. No. 08/264,581 filed Jun. 23, 1994, now U.S. Pat. No. 5,585,096.

#### ***Priority***

2. As indicated in the withdrawn Final office action mailed on 04/03/2007, in the response to Non-Final rejection mailed on 10/4/2006, Applicant pointed out that the Examiner omitted priority claim to U.S. Patent Application No. 08/264,581 (now Patent No. 5,585,096), filed June 23, 1994. The Examiner acknowledges that the information regarding omitted priority to U.S. Patent Application No. 08/264,581 (now Patent No. 5,585,096) was indeed submitted by

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applicants as amendments of Specification filed on 9/8/2004. It is noted that the specification of U.S. Patent Application No. 08/264,581 (now Patent No. 5,585,096), filed June 23, 1994 supports the claims of instant application (See forth paragraph, column 4, U.S. Patent No. 5,585,096). Therefore, the priority of claims of instant application is determined to be 06/23/1994.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 7-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is unclear in reciting the phrase “relative to wild type”. It is well established in the literature that polymorphisms exists among different isolates of HSV (Herpes Simplex Virus). Therefore, it’s not clear which isolate of HSV is considered as the “wild type”.

The Examiner notes that claim 1 of US patent No. 6,699,468, issued on 03/02/2004 (same inventors of instant application) is a method of eliciting an immune response comprising administration of the HSV of instant application. The phrase “relative to wild type” is *not* present in claim 1 of US patent No. 6,699,468. Removal of the phrase “relative to wild type” would be remedial.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (c) or 1.321 (d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Previous provisional rejection of claims 7-18 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-29 of copending Application No. 10/788,410, is **withdrawn** because a terminal disclaimer has been filed on 07/06/2007.

5. Previous rejection of claims 7-18 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35-39, 43-46 of copending Application No. 11/097,391, is **withdrawn** because Applicant's arguments were found persuasive.

Specifically, in the response filed on 07/03/2007, Applicant argues that the present application has a filing date of December 31, 2003, while the '391 application has a filing date of

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April 4, 2005. Pursuant to MPEP 804, "[i]f a 'provisional' nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer..." Accordingly, Applicants respectfully request withdrawal of the provisional double patenting rejection in the present application, which was filed earlier than the co-pending '391 application.

6. Claims 7-18 are *newly* rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U. S. Patent number 5,585,096, issued on 12/17/1996. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to the same herpes virus construct with mutations in both  $\gamma$ 34.5 gene and ribonucleotide reductase gene. In each case the claims as a whole set forth a herpes virus comprising an alteration in  $\gamma$ 34.5, an alteration in the ribonucleotide reductase gene, and a gene of interest (specified as non-herpes simplex virus in instant application). It is noted that claims 1 and 2 of U. S. Patent number 5,585,096, issued on 12/17/1996 reads on herpes virus comprising a non-functional (i.e. mutated)  $\gamma$ 34.5 gene, a non-functional (i.e. mutated) ribonucleotide reductase gene, with or without insertion of a heterologous gene of interest. Therefore, the scope of claims 1 and 2 of U. S. Patent number 5,585,096, is broader than the scope of claims 7-18 of instant application. Claims 7-18 (species) of instant application anticipate claims 1 and 2 (genus) of U. S. Patent number 5,585,096.

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The Examiner further notes that upon review of the Restriction Requirement of application 08/264,581 filed Jun. 23, 1994, now U.S. Pat. No. 5,585,096, there was no restriction between the recited HSV construct with versus without an insert.

This is an obviousness-type double patenting rejection because the conflicting claims have in fact been patented.

*Conclusion*

7. No claim is allowed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Wu Cheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-273-3157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the supervisory patent examiner, Peter Paras, can be reached on (571) 272-4517. The fax number for TC 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Wu-Cheng Winston Shen, Ph. D.

Patent Examiner

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/Valarie Bertoglio, Ph.D./

Primary Examiner

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